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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/525,808

03/15/2000

Athanasius A Anagnostou

5218-39C

9764

20792 7590 02/03/2009  
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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

02/03/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/525,808	<b>Applicant(s)</b> ANAGNOSTOU ET AL.	
	<b>Examiner</b> CHRISTOPHER H. YAEN	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16,22,31,33,42,44 and 47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16,22,31,33,42,44 and 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/21/09</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Prosecution Application***

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/21/2009 has been entered.
2. Claims 1-15, 17-21,23-30, 32, 34-41,43, and 45-46 are canceled without prejudice or disclaimer.
3. Claims 16,22, 31, 33, 42, 44, and 47 are pending and examined on the merits.
4. The Information Disclosure Statement filed on 1/21/2009 is acknowledged and considered. A signed copy of the IDS is attached hereto.

#### ***Claim Rejections Maintained - 35 USC § 103***

5. The rejection of claims 16,22,31,33,42,44, and 47 under 35 USC § 103(a) as being obvious over Silvestris et al (Ann. Hematol. 1995, vol. 70:313-318; previously cited) in view of Bukowski *et al* (Blood, J of the American Society of Hematology, 1994; vol. 84(10, Supp. 1):129A; previously cited) and Chugai (JP 02 096535) is maintained for the reasons of record. Applicant argues the newly amended claim language overcomes the instant rejection. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. The combination of

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the cited references renders obvious the instantly claimed invention. In particular, Silvestris *et al* teach the administration of EPO within the range of the claimed dosages (ie 150 U/kg, see page 314) in combination with chemotherapeutics (ie VMCP or vincristine, melphalan, cyclophosphamide, and prednisone). Bukowski *et al* teach the administration of cisplatin, carboplatin, nonplatinum in combination with "PROCRIT" a branded version of EPO. Chugai teaches the use of EPO and chemotherapeutics and the administration of the EPO via different routes of administration, such as IV or SC. Applicant has not provided any objective evidence to overcome the rejections already of record. Therefore, the rejection of record is maintained for the reasons already set forth in previous office actions.

### ***Claim Rejections Maintained - 35 USC § 102***

6. The rejection of claims 16 and 33 under 35 USC § 102(b) as being anticipated by Silvestris *et al* (Ann. Hematol 1995; 70(6):313-318; previously cited) is maintained for the reasons of record. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. Applicant has not provided any arguments to rebut the prima facie case of anticipation set forth in the previous office action. Therefore, the rejection of claims is maintained for the reasons of record.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER H. YAEN whose telephone number is (571)272-0838. The examiner can normally be reached on Monday-Friday 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher H Yaen/  
Primary Examiner, Art Unit 1643